



medilogAR
EU MDR Declaration of Conformity
Rev. 01

SCHILLER
The Art of Diagnostics

Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland
SRN: CH-MF-000012722

EU Authorised Representative: SCHILLER Medizintechnik GmbH
Otto-Lilienthal-Ring 4, 85622 Feldkirchen, Germany
SRN: DE-AR-000006934

QMS: Q5 041505 0115

EC-certificate: G10 041505 0132

Notified Body: TÜV SÜD Product Service GmbH, ID 0123

Device Information				
Trade Name	medilogAR			
Product Type	0203 (Non-Invasive) ECG Holter Recorder			
Intended Purpose	The medilogAR is used to record a 3-channel ECG. The recorder is designed for a measuring duration of more than 24 hours and is therefore worn by the patient throughout the day. The preparation for the recording (attaching electrodes, etc.) is performed by the technician or doctor.			
Risk Class acc. to Annex VIII MDR	IIa			
GMDN Code	35162			
EMDN Code	Z120504			
Basic UDI-DI	761336500000001353			
Conformity Assessment acc. to MDR	Annex IX Chapters I and III			
REF Number	REF #	GTIN	Device Name - Description	Date added
	3.920740	07613365002096	medilogAR (Main device)	2025-04-16
	1A.306000	07613365002102	medilogAR (Kit)	2025-04-16
Standards Applied and Common Specifications	ISO 13485:2016 (EN ISO 13485:2016 + AC:2018 + A11:2021) ISO 14971:2019 (EN ISO 14971:2019/A11:2021) IEC 60601-1:2020 (EN 60601-1:2006/A13:2024) IEC 60601-1-2:2020 ed. 4.1 (EN 60601-1-2:2015 + A1:2021) IEC 60601-1-11:2020 (EN 60601-1-11:2015 + A1:2021) IEC 60529:1989 + A1:1999 + A2:2013 (EN 60529:1991 + A1:2000 + A2:2013) IEC 60601-2-47:2012 ed. 2.0 (EN 60601-2-47:2015) IEC 62304:2015 ed. 1.1 (EN 62304:2006 + Cor.:2008 + A1:2015) IEC 62366-1:2020 ed. 1.1 (EN 62366-1:2015 + AC:2015 + A1:2020) IEC 60601-1-6:2020 ed. 3.2 (EN 60601-1-6:2010 + A1:2015 + A2:2021) ISO 10993-1:2018 ed. 5.0 (EN ISO 10993-1:2020) ISO 20417: 2021 ed. 1.0 (EN ISO 20417:2021) ISO 15223-1: 2021 ed. 4.0 (EN ISO 15223-1:2021)			

We, the undersigned, declare that the medical device described above is in conformity with the applicable provision of the MDR (EU) 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC



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The products are CE marked with notified body number.



RoHS 2 and 3

We, the undersigned, further declare that the medical device described above is in conformity with the applicable provision of the *Directive 2011/65/EU "Restriction of the use of certain hazardous substances in electrical and electronic equipment"* and its amended *Directive 2015/863/EU*.

This declaration of conformity is issued under the sole responsibility of SCHILLER AG. This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of **SCHILLER AG**

Date of Issue: 2025-04-16

Place of Issue: Baar, Switzerland

Name: AYNUR ASLANOVA

Name: STEFAN BIGLER

Title / Function: *HEAD OF QUALITY
MANAGEMENT*

Title / Function: *HEAD OF REGULATORY
AFFAIRS*

Signature

SCHILLER AG
Altgasse 68
H-6341 Baar/Switzerland

Signature



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Appendix 01 List of compatible medical devices and accessories covered by this declaration

SCHILLER AG REF No.	Device name	REF No. as per Label	Legal Manufacturer
-	-	-	-

Appendix 02 List of compatible non-medical device(s), spare parts, and components covered by this declaration

SCHILLER AG REF No.	Description / Device name	GTIN/EAN (if available)
2.400176	5-wire patient cable push-button, 82 cm, medilogAR (MD-spare part)	07613365001952
2.400177	7-wire patient cable push-button, 82 cm, medilogAR (MD-spare part)	07613365001945
2.100850	Alcaline battery LR03, type AAA, 1.5 V	-
2.610063	Protective case (for unit protection and patient attachment)	-
2.610064	Battery compartment cover	-
2.610065	Transparent front cover	-
2.610066	Micro USB cable	-
2.610067	MicroSD card with Adapter	-
2.156096	medilogAR Neck Belt (compatible with 2.610063)	-
2.310426	USB cable 2.0 high speed, magnetic adapter, 1.0 m	-
2.310427	USB cable 2.0 high speed, magnetic adapter, 0.3 m	-

Change History

Description of Change	Revision
First version	01